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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/151,409 09/10/98 DALE

J 481112.410

EXAMINER

HM12/0216

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LEE, J.

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

02/16/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/151,409

Applicant(s)

Date

Examiner

Li Lee

Group Art Unit

1645



☒ Responsive to communication(s) filed on Nov 29, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-11 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-11 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 12

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicant's amendment filed on Nov 29, 1999 (Paper Number 14) has been received and entered. Claims 1-11 are pending in the instant application.
2. Items listed on form PTO-1449 filed on Nov 05, 1999 have be considered by the examiner.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

3. The rejection of claims 1-11 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of Applicant's remarks.

Rejections Maintained

4. The rejection of claims 1, 5, and 9-11 under 35 U.S.C. 102(b) as being anticipated by Dale (J Immunol.151(4): 2188-2194, 1993) or Dale (Vaccine 14 (10):944-8, 1996 (Jul)) is maintained for reasons made of record in Paper No 11, mailed 05/26/99.

Applicant's are asserting that Dale (JI)/Dale (Vaccine) does not disclose a fusion peptide having a peptide located C-terminal to any of the immunogenic peptides which protects the immunogenic portion and does not disclose a peptide located C-terminal to an immunogenic peptide that is not required to stimulate an immune response. As applicant states, the C-terminal peptide could be a part of a Streptococci protein but not required for immunogenicity (Amendment, page 2). Therefore, the peptide of Dale meets the limitation because the C-terminal

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peptide (it can be as few as 2-3 amino acids in length because the claims do not require a length of the C-terminal peptide) of Dale which is part of the Streptococci protein can be used to stimulate an immune response though it is not required to do so. Applicant's further assert that the peptide of Dale is not protected by the C-terminal peptide since it was less effective in eliciting antibody titer. However, the claimed polypeptide does not require full protection to the immunogenic polypeptide. The immunogenicity of Dale's peptide is protected by the C-terminal polypeptide because the peptide of Dale is covalently linked to KLH for the protection of the immunogenicity. The peptide of Dale is immunogenic and has elicited protective immune responses against group A Streptococci in the test hosts.

5. The rejection of claims 5 and 6 under 35 U.S.C. 102(b) as being anticipated by Dale (J Exp Med 163:1191-1202, 1986) for reasons made of record in Paper No 11, mailed 05/26/99.

Applicant's are asserting that Dale (86) has the same deficiencies as Dale (JI)/Dale (Vaccine). In addition, the conjugate molecule KLH is structurally dissimilar from a fusion protein and the conjugation reaction would not result in a polypeptide having a non-immunogenic peptide located C-terminal to an immunogenic peptide or form a contiguous polypeptide backbone and a conjugate molecule is structurally dissimilar from a fusion protein. As discussed above, when the C-terminal peptide of Dale is covalently linked to KLH, the immunogenicity of Dale's peptide is protected by the C-terminal polypeptide. Because the claims recite an open claim language, e.g., comprising, the polypeptide of Dale (J Exp Med 163:1191-1202, 1986) still meets the limitation of the claims though the structure of KLH is different from

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a streptococci protein. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., form a contiguous polypeptide backbone) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The specification teaches that the polypeptide of the present invention can be synthesized chemically or generated recombinantly (page 8, lines 8-13). The term "fusion" is generally interpreted as "a union by or as if by melting: a merging of diverse, distinct, or separate elements into a unified whole" (Merriam Webster's Collegiate Dictionary, Tenth Edition, 1997, page 474). Therefore, the synthesized polypeptide of Dale (J Exp Med 163:1191-1202, 1986) meet the limitation of the claims.

6. The rejection of claims 5 and 7 under 35 U.S.C. 102(b) as being anticipated by Beachey (J Immunol. 136(3):2287-92, 1986) is maintained for reasons made of record in Paper No 11, mailed 05/26/99.

Applicant's are asserting that Beachey (J Immunol. 136(3):2287-92, 1986) has the same deficiencies as discussed above with Dale (J Exp Med 163:1191-1202, 1986). A conjugate is not a fusion protein and does not contain a non-immunogenic peptide C-terminus to an immunogenic peptide.

As discussed above, when the C-terminal peptide of Beachey which is part of the polypeptide is covalently linked to another polypeptide tetanus toxoid, the immunogenicity of

Beachey's peptide is protected by the C-terminal polypeptide because the peptide is covalently linked to tetanus toxoid for the protection of the immunogenicity. The peptide is still immunogenic and has elicited protective immune responses against group A streptococci in the test hosts.

7. The rejection of claims 1 and 2 under 35 U.S.C. 103(a) as being unpatentable over Dale (J Exp Med 163:1191-1202, 1986) and Dale ((J Immunol.. 151(4): 2188-2194, 1993) is maintained for reasons made of record in Paper No 11, mailed 05/26/99.

Applicant's are asserting that Examiner has not established a suggestion in the cited art to make the claimed invention and has impermissibly interpreted the prior art. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Since the rejection under 102 being anticipated by Dale does not fail (as discussed above), neither does the 103 based on these references.

8. The rejection of claims 1 and 3 under 35 U.S.C. 103(a) as being unpatentable over Beachey (J Immunol. 136(3):2287-92, 1986) and Dale ((J Immunol.. 151(4): 2188-2194, 1993) is maintained for reasons made of record in Paper No 11, mailed 05/26/99.

Applicants traverse these grounds of rejection for essentially the same reason discussed above. Applicant's are asserting that Examiner has not established a suggestion in the cited art to make the claimed invention and has impermissibly interpreted the prior art. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Since the rejection under 102 being anticipated by Beachey does not fail (as discussed above), neither does the 103 based on these references.

9. The rejection of claims 1 and 4 under 35 U.S.C. 103(a) as being unpatentable over Dale (J Immunol. 151(4): 2188-2194, 1993) and Beall (J Clin Microbiol 34 (4):953-8, 1996) is maintained for reasons made of record in Paper No 11, mailed 05/26/99.

In response to applicant's argument that Beall does not suggest the assembly of a fusion polypeptide containing a protective peptide C-terminal to the immunogenic peptide, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of

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the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Lee, M.D., Ph.D. whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995.

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Li Lee, M.D., Ph.D.
February 10, 2000



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